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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/GB2004/005185

International filing date (day/month/year)
13.12.2004

Priority date (day/month/year)
12.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61B6/00

Applicant
TISSUOMICS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

Authorized Officer



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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

see separate sheet

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-24
Inventive step (IS)	Yes: Claims	
	No: Claims	1-24
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and / or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

X1=Geraki et al.: "X-ray fluorescence and energy dispersive ...", Oct. 2003
X2=Farquharson et al.: "The use of combined trace element ...", Jun. 2002
DPX3=Geraki et al.: "X-ray fluorescence and energy dispersive ...", Jan. 2004
X4=Haston et al.: "Raman Microscopy and X-ray Diffraction ...", Oct. 2003
X5=Kleuker et al.: "Feasibility study of x-ray diffraction ...", 1998
X6=Barroso et al.: "X-ray diffraction microtomography ...", 2001
DX7=Farquharson et al.: "Multivariate Calibration for ...", 1997
DX8=AL-Bahri et al.: "Electron Density of Normal and Pathological ...", 1998
X9=Duvauchelle et al.: "Rayleigh to Compton ratio computed tomography ...", 2000
X10=Yuasa et al.: "Incoherent-Scatter Computed Tomography ...", 1997
X11=Harding et al.: "X-ray imaging with Compton-scatter radiation", 1983
X12=Duvauchelle et al.: "Effective atomic number in the Rayleigh ...", 1999
X13=Huddleston et al.: "Compton Scatter Densitometry in Cancellous Bone", 1979
X14=Battista et al.: "Compton Scatter Imaging of Transverse Sections ...", 1977
X15=Tothill: "Methods of bone mineral measurement", 1989
X16=Puumalainen et al.: "Assessment of Fat Content of Liver by a Photon ...", 1977

Section II

Assuming that the relevant date (Rule 43bis.1 and 64.1) is the claimed priority date the references to DPX3 in the following paragraphs are not relevant and provided only for the sake of completeness.

Section IV

The common concept of claims 1-14 on the one hand and claims 15-24 on the other hand resides merely in a

method for analysing and/or characterising body tissue using a measurable tissue property.

This concept is anticipated by each cited document (see also application page 1) and thus not new, let alone inventive as required by Rule 13.1 PCT. Therefore the application lacks unity of invention and contains the two inventions listed in the search report.

Section V

1.1. Independent claims 1 and 2 define in slightly different words the same subject matter and are thus not concise contrary to Art.6 PCT.

1.2. The subject matter of independent claims 1 and 2 is anticipated by each of the following documents:

X1, X2, DPX3 stemming from the inventors: see whole documents

X4: the two components of data are Raman microscopy and x-ray diffraction

X5: the plurality of components of data are the intensities at the various diffraction angles including the zero angle (transmission), compare dependent claim 8 of the application

X6: the three components of data are the intensities at the two material specific diffraction angles and at zero angle (transmission), see in particular Fig.8,9 of X6; compare dependent claim 8 of the application

DX7: the plurality of components of data are the intensities at the various energies

X9: the two components of data are Rayleigh and Compton scattering; for "tissue" see p.23, right column, lines 6,7 and p.24, left column, second paragraph

X10: the two components of data are xrf and compton scattering, see title

X12: abstract

X16: the two components of data are coherent scattering and compton scattering

2.1. Claim 11 defines explicitly or implicitly all features defined in claims 1 or 2 and thus depends on claims 1 and 2 within the meaning of Rule 6.4(a) PCT. However claim 11 infringes this rule, since it redefines the features already defined in claims 1 or 2 instead of referring to claims 1 or 2 and defining only the additional features.

2.2. The subject matter of dependent claims 3-14 is likewise anticipated by the documents cited in the search report. The subject matter of dependent claims 10-14 is in particular anticipated by each of X1, X2, DPX3, X5 (the calibration using "basis functions" is described in the passages of X5 cited in the search report. The plurality of measurable tissue properties are the intensities at the various diffraction angles and the tissue characteristic is the concentration of a particular material) and DX7 (the plurality of measurable tissue properties are the intensities at the various energies and the tissue characteristic is the content of a particular material).

3. The subject matter of independent claim 15 is anticipated by each of the following documents:

DX8: see page 1677

X9: title and abstract; for "tissue" see p.23, right column, lines 6,7 and p.24, left column, second paragraph

X10: title

X11: abstract, Fig.11

X12: abstract

X13: for "cancellous bone tissue" and "compton scatter" see abstract

X14: for "compton scatter" and tissue "bone, lung" see abstract

X15: for bone tissue and compton scattering see p.559-560

X16: abstract

With respect to X13 and X15 it is to be noted that claim 15 does not exclude bone tissue, although the application acknowledges on p.3,l.22ff and on p.4,l.18ff that compton scatter bone densitometry is well known in the field.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/005185

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4.1. Claim 24 defines implicitly all features defined in claim 15 and thus depends on claim 15 within the meaning of Rule 6.4(a) PCT. However claim 24 infringes this rule, since it redefines the features already defined in claim 24 instead of referring to claim 15 and defining only the additional features.

4.2 The subject matter of dependent claims 16-24 is likewise anticipated or rendered obvious by any of documents DX8-X16. The correction for attenuation as defined in claims 19-21 is for example disclosed in DX8 (p.1677, right col., 2nd para.), X9 (p.29), X10 (p.1761, right col., 2nd para.; Fig.3), X11, X13 (p.310-312), X14 (p.238-240; p.242,l.1-6) and X15 (p.559,560). That the features of claims 19-21 are well known is even explicitly stated on p.4,l.23ff of the application. For claim 24 see for example X12, DX8 (p.1680, left column, line 6 from bottom "calibration samples") or X16 (Fig.4).

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